DETAILED ACTION

This office action is in response to applicant's request for continued examination filed on October 23, 2009 and the reply filed on March 16, 2010 in response to a Restriction/Election requirement.

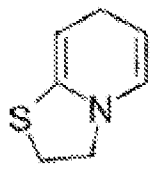
Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Election/Restrictions

Applicant had previously elected, without traverse, the invention of claims 112-123 (see office action dated 07/23/09)

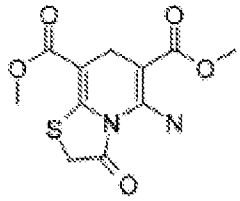
Applicant's further election of the CORE structure:



which is encompassed by claims 112-123, in the reply filed on March 16, 2010, is acknowledged.

Since this was an election corresponding to a restriction requirement, all the other structures within the above claims (112-123) that are not encompassed within the above CORE structure are withdrawn from consideration as non-elected inventions.

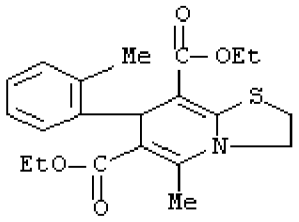
Applicant further election of the following species, corresponding to the above CORE structure:



also known as D3.008, according to the specification, is also acknowledged.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a).

Since the above elected species is free of prior art, the examination was expanded to the following species: 7H-Thiazolo[3,2-a]pyridine-6,8-dicarboxylic acid, 2,3-dihydro-5-methyl-7-(2-methylphenyl)-6,8-diethyl ester (CAS# 50620-60-5, from now on compound A):



Compound A

Status of Claims

Claims 112-131 are currently pending and are the subject of this Office Action.

The elected species (D3.008) reads on the following claims: 112-113, 115-116 and 118-123.

The expanded species (Compound A) reads on the following claims: 112, 115, and 118-123.

The combined set of claims that read on one or both species and, as a consequence, are presently under examination are: 112-113, 115-116 and 118-123. These claims are presently under examination as they relate to the above CORE structure. Everything else within the claims is withdrawn from consideration.

Claims 114, 117 and 124-131 are withdrawn from further consideration.

Priority

The present application is a 371 of PCT/EP04/11645 filed on 10/15/2004 and claims priority to foreign application: GERMANY 103 48 022.6 filed on 10/15/2003.

Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a certified English translation of the foreign application must be submitted in reply to this action. 37 CFR 41.154(b) and 41.202(e).

Failure to provide a certified translation may result in no benefit being accorded for the non-English application.

Information Disclosure Statement

The Information Disclosure Statement filed on 03/16/2010 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. A signed copy of the IDS is attached hereto.

Rejections and/or Objections and Response to Arguments

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated (Maintained Rejections and/or Objections) or newly applied (New Rejections and/or Objections, Necessitated by Amendment or New Rejections and/or Objections not Necessitated by Amendment). They constitute the complete set presently being applied to the instant application.

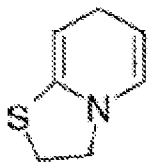
Claim Rejections - 35 USC § 102 (New Rejection)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

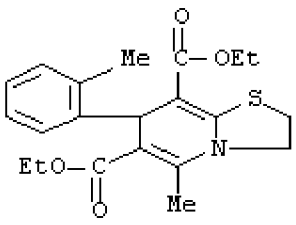
> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 112, 115, 120, and 123 are rejected under 35 U.S.C. 102(b) as being anticipated by Meyer et. al. (US 4,053,614).

Claims 112, 115 and 123 recite a pharmaceutical or cosmetic composition comprising at least one of a pharmaceutically acceptable carrier and a pharmaceutically or cosmetically acceptable adjuvant and at least one active ingredient selected from the CORE structure:



which encompasses compound A (expanded species):



For claims 112, 115 and 123, Meyer teaches a pharmaceutical composition comprising compound A (see column 1 lines 11-30 and column 11, Example 2). Meyer

further teaches that the pharmaceutical compositions further comprise pharmaceutical carriers and adjuvants (see column 9, lines 8-14).

The statement in claim 115: "suitable for use in a method of inhibiting an activity of at least one enzyme selected from dipeptidyl peptidase IV and analogous enzymes in a subject in need thereof" and the statement in claim 123: "wherein the composition is suitable for use as a cosmetic composition", are considered an intended uses and do not add any new limitation to the claims. *Catalina Mktg. Int'l, Inc. V. Coolsavings.com*, Inc., 289 F.3d 801, 808, 62 USPQ2d 1781, 1785 (fed. Cir. 2002). "The recitation of a new intended use for an old product does not make a claim to that old product patentable." *In re Schreiber*, 44 USPQ2d 1429 (Fed. Cir. 1997).

Claim 120 further limits claim 112, wherein the composition is suitable for at least one of oral, transdermal, etc., administration.

For claim 120, Meyer further teaches the oral administration of the pharmaceutical composition (see column 9, line 42).

Claim Rejections - 35 USC § 103 (New Rejection)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

> invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1) Claim 118 is rejected under 35 U.S.C. 103(a) as being unpatentable over Meyer et. al. (US 4,053,614) in view of Ding et. al. (US 6,120,536, cited in prior office action).

Claim 118 further limits claim 112, wherein the composition is comprised in a coating of a stent.

Meyer teaches all the limitations of claim 118 (see 102(b) rejection above), except for the composition being comprised in a coating of a stent. However, Ding teaches that coating stents with pharmaceutical agents is common practice in the pharmaceutical industry (see column 1, last paragraph and column 2, first and second paragraphs).

At the time of the invention, it would have been *prima facie* obvious for the skilled artisan to have the pharmaceutical composition of claim 112 comprised in a coating of a stent as taught by Ding, with the motivation of having a better delivery of the active ingredient compound A, thus resulting in the practice of claim 118 with a reasonable expectation of success.

2) Claims 119 and 121 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meyer et. al. (US 4,053,614) in view of Papathanassiu (US 6,528,489, cited in prior Office Action).

Claim 119 further limits claim 112, wherein the composition is suitable for topical administration.

Meyers teaches all the limitations of claim 119 (see 102(b) rejection above), except for being suitable for topical administration. However, Papathanassiu teaches

that topical administration of active ingredients is common practice in the pharmaceutical industry (see column 5, second paragraph).

At the time of the invention, it would have been *prima facie* obvious for the skilled artisan to have the pharmaceutical composition of claim 112 suitable for topical administration as taught by Papathanassiu, with the motivation of having a better form of administration for compound A, thus resulting in the practice of claim 119 with a reasonable expectation of success.

Claim 121 further limits claim 112, wherein the composition is present as a cream an ointment, a paste, and a gel.

Meyer teaches all the limitations of claim 121 (see 102(b) rejection above), except for the composition being a cream, an ointment, a paste or a gel. However, Papathanassiu teaches that creams, ointments, pastes and gels are common formulations of active ingredients in the pharmaceutical industry (see column 5, second paragraph).

At the time of the invention, it would have been *prima facie* obvious for the skilled artisan to have the pharmaceutical composition of claim 112 in a form of a cream, ointment, past or gel as taught by Papathanassiu, with the motivation of having a better formulation for the active ingredient (compound A), thus resulting in the practice of claim 121 with a reasonable expectation of success..

3) Claim 122 is rejected under 35 U.S.C. 103(a) as being unpatentable over Meyer et. al. (US 4,053,614) in view of Aberg et. al. (US 2003/0092635)

Claim 122 further limits claim 112, wherein the composition is present in combination with at least one of a depot matrix, a hydrocolloid dressing, a plaster, a micro-sponge and a prepolymer.

Meyer teaches all the limitations of claim 122 (see 102(b) rejection above), except for being present in combination with at least one of a depot matrix, a hydrocolloid dressing, a plaster, a micro-sponge and a prepolymer. However, Aberg teaches that micro-sponges are common use in the pharmaceutical industry in formulations of small molecules (see paragraph [0012]).

At the time of the invention, it would have been *prima facie* obvious for the skilled artisan to have the pharmaceutical composition of claim 112 present in a micro-sponge as taught by Abergr, with the motivation of better delivering the active ingredient (compound A), thus resulting in the practice of claim 122 with a reasonable expectation of success.

Claim Objections

Claims 113 and 116 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The compound of claims 113 and 116 is free of prior art.

Withdrawn Rejections and/or Objections

Claims rejected under 35 USC 103(a)

Due to Applicant amendment, the previously examined species: Zaleplon (CAS# 151319-34-5 for the neutral form and 899446-93-6 for the HCl form) no longer reads on the instant claims.

Rejection under 35 USC 103(a)) is withdrawn.

However, upon expansion to the following species: 7H-Thiazolo[3,2-a]pyridine-6,8-dicarboxylic acid, 2,3-dihydro-5-methyl-7-(2-methylphenyl)-6,8-diethyl ester (CAS# 50620-60-5, compound A), new USC 102 (b) and 103(a) rejections, necessitated by amendment (see above) are applied.

Conclusion

No claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCOS SZNAIDMAN whose telephone number is (571)270-3498. The examiner can normally be reached on Monday through Thursday 8 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MARCOS SZNAIDMAN/
Examiner, Art Unit 1612
April 14, 2010.